

Louisiana Office of Public Health Laboratories	
Test Name	Xtag Cystic Fibrosis Mutation Detection Kit
PHL Location	Central Laboratory 1209 Leesville Avenue Baton Rouge, Louisiana 70802
CPT Code	83516
Synonyms	CF
Brief Description of Test	To simultaneously detect and identify a panel of mutations and variants in the cystic fibrosis transmembrane conductance regulator (CFTR) gene in human blood specimens.
Possible Results	0-Mutations, 1Mutation or 2Mutations
Reference Range	0-Mutations
Specimen Type	Neonatal Dried Blood Spot
Specimen Container(s):	Shipping Envelopes
Minimum volume accepted:	Minimum of 2 completely filled blood spot circles
Collection Instructions	Blood Specimens should be taken directly from a heel prick onto filter paper and, allowed to dry for at least 3 hours in a horizontal position.
Storage and Transport Instructions	Storage of samples in an environment with elevated temperatures and humidity increases the risk of false positive screening results. Transport or mail the specimen to the laboratory with 24 hours of collection.
Causes for Rejection	Specimen > 14 days old, clotted or layered, serum rings, scratched or abraded, insufficient quantity for testing, not completely dry before mailing, blood applied to both sides of the filter paper, diluted discolored or contaminated, collection using capillary tubes containing EDTA, >12 months old, circles not completely filled.
Limitations of the Procedure	Samples spot not uniformly saturated with blood - sample spots punched too close to the edge of the blood spot - poorly collected and improperly dried specimens - non-eluting blood spot due to deterioration of sample caused by exposure to heat and humidity - contamination of blood spot filter paper with fecal material Heterophilic antibodies in the sample may interfere with the assay (16,17). Hematocrit values in the blood sample may affect the measured hTSH concentration
Interfering Substances	N/A
References	Luminex xTAG Cystic Fibrosis Kit Package Insert
Additional Information	N/A
Release Date	11/2013
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